NOV - 6 2000

510(K) SUMMARY

K000023

FRIENLY LIGHT™ ER:YAG PULSED LASER

SUBMITTED BY:

PRINCETON REGULATORY ASSOCIATES
116 Village Boulevard, Suite 200
Princeton, NJ 09540

September 13, 2000

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Thomas Becze

PRINCETON REGULATORY ASSOCIATES

Phone: (609) 951-9596 Fax: (609) 951-0003

2. Device Name and Classification:

TRADE NAME: ***FRIENDLY LIGHT***™ **ER:YAG PULSED LASER**

CLASSIFICATION NAME: ERBIUM: YTTRIUM ALUMINUM GARNET (ER:YAG) LASER
CLASSIFICATION PANEL: GENERAL AND PLASTIC SURGERY; PANEL 79
CFR SECTION: 21 CFR §878.4810
Device Class: Class II

Laser Safety Class: Class IV

3. Substantial Equivalence:

The ***Friendly Light***™ **Er:YAG Pulsed Laser** is substantially equivalent to the current, legally marketed **MCL-29 DERMABLATE**® Er:YAG Laser System (K980361; K962148). The ***Friendly Light***™ **Laser** is not materially different in use from the predicate device. There are modest improvements, ease of use and safety, which differentiate the subject laser from its predicate.

4. Device Description:

The ***Friendly Light*™ Laser** is a pulsed erbium doped yttrium-aluminum-garnet (Er:YAG) laser. It outputs laser light with a wavelength of 2940 nm, a wavelength very efficiently absorbed by the skin. When properly used, it will remove the outermost layer of skin to a depth of approximately 15 microns without making physical contact with the patient.

5. Intended Use of the Device:

The FriendlyLight Er:YAG is intended for coagulation, vaporization ablation and/or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology (skin around the eyes). This includes skin resurfacing and the treatment of wrinkles.

Er:YAG lasers have been used successfully in the following specialties:

- General Surgery
- Podiatry
- Urology
- Gynecology
- Ear, Nose, and Throat (ENT)
- Oral and Maxillofacial

6. Summary of Technological Characteristics of the Device Compared to the Predicate Device:

The ***Friendly Light*™ Er:YAG Pulsed Laser** is substantially equivalent to the current, legally marketed **MCL-29 DERMABLATE®** Er:YAG Laser System (K980361; K962148). There are modest improvements, ease of use and safety, which differentiate the subject laser from its predicate.

Respectfully submitted,

Thomas Beczek
President

PRINCETON REGULATORY ASSOCIATES

TB:dv

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 2000

Innotech USA, Inc.
c/o Mr. Thomas Becze
President
Princeton Regulatory Associates
116 Village Boulevard, Suite 200
Princeton, New Jersey 08540-5799

Re: K000023
Trade Name: Friendly Light™ Er: YAG Pulsed Laser
Regulatory Class: II
Product Code: GEX
Dated: July 28, 2000
Received: August 14, 2000

Dear Mr. Becze:

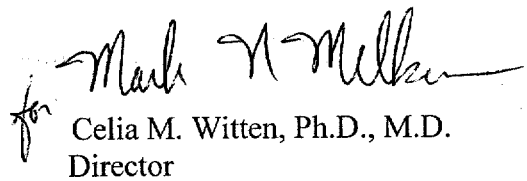
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) NUMBER IF KNOWN): **K000023**

DEVICE NAME: ***FRIENDLY LIGHT™* ERBIUM YAG LASER**

INDICATIONS FOR USE:

The FriendlyLight Er:YAG is intended for coagulation, vaporization ablation and/or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology (skin around the eyes). This includes skin resurfacing and the treatment of wrinkles.

Er:YAG lasers have been used successfully in the following specialties:

- General Surgery
- Podiatry
- Urology
- Gynecology
- Ear, Nose, and Throat (ENT)
- Oral and Maxillofacial

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

PRESCRIPTION USE ✓ OR OVER-THE-COUNTER USE _____

(PER 21 CFR 801.109)

(OPTIONAL FORMAT 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000023